[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Chris Kornak at 240-627-3705 or *Chris.Kornak@nih.gov*. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Replication-Competent Adenovirus Type 4 SARS-CoV-2 Vaccines and Their Use

Description of Technology:

NIAID has produced recombinant adenovirus type 4 (Ad4), SARS-CoV-2 spike, vectors for administration to humans. These recombinant vaccines permit rapid development of high levels of neutralizing antibodies to SARS-CoV-2 in experimental animals. This vaccine is designed to improve the durability of the immune response by inducing mucosal and systemic immunity. Further, this system should be incredibly

simple and efficient when producing vaccine at scale. This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Vaccine composition(s)

Competitive Advantages:

- Stimulates a durable immune response;
- Induction of mucosal and systemic immunity;
- Potential for transmission interruption;
- Intranasal administration minimizes the impact of pre-existing immunity;
- Notable improvement for manufacturing yield and cost, ease of administration, and distribution as compared to current candidates.

Inventor: Mark Connors, M.D. (NIAID)

Publications: Matsuda et al. Journal of Clinical Investigation, 2021 (https://doi.org/10.1172/JCI140794). Matsuda et al., Science Immunology 2019 (https://doi.org/10.1126/sciimmunol.aau2710).

Intellectual Property: HHS Reference E-055-2021; Application No. 63/138,221.

Licensing Contact: To license this technology, please contact Chris Kornak at chris.kornak@nih.gov

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this invention. Interested parties should have the ability to manufacture viruses under cGMP, suitable for Phase 1-2 testing by NIAID. Capabilities for further clinical development, and

experience with Phase 3 testing, licensure, and rollout are preferred. For collaboration opportunities, please contact Chris Kornak at chris.kornak@nih.gov.

Dated: January 29, 2021.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021-03044 Filed: 2/12/2021 8:45 am; Publication Date: 2/16/2021]